

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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UNITED STATES OF AMERICA, :
 :
Plaintiff, : Case No. 11 Civ. 8196 (CM)
 :
v. : **NOVARTIS PHARMACEUTICALS**
 : **CORPORATION’S ANSWER TO THE**
 : **FIRST AMENDED COMPLAINT IN**
NOVARTIS PHARMACEUTICALS : **INTERVENTION OF THE STATES OF**
CORPORATION, : **GEORGIA, ILLINOIS, INDIANA,**
 : **MARYLAND, MICHIGAN, NEW JERSEY,**
Defendant. : **NEW YORK, OKLAHOMA AND**
 : **WISCONSIN (DE 257)**
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Defendant Novartis Pharmaceuticals Corporation (“Novartis”), for its Answer to the First Amended Complaint in Intervention of the States of Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma and Wisconsin (“Complaint” by the “States”), dated September 18, 2014, states as follows:

1. Denies the allegations set forth in numbered paragraph 1 of the Complaint.
2. Denies the allegations set forth in numbered paragraph 2 of the Complaint.
3. Denies the allegations set forth in numbered paragraph 3 of the Complaint.
4. Denies the allegations set forth in the first, second and third sentences of numbered paragraph 4 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the fourth sentence of numbered paragraph 4.
5. Denies the allegations set forth in numbered paragraph 5 of the Complaint.
6. Denies the allegations set forth in numbered paragraph 6 of the Complaint.
7. Denies the allegations set forth in numbered paragraph 7 of the Complaint.

8. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 8 of the Complaint, except admits that docket entry number 47 is Relator's First Amended Complaint, dated April 18, 2013.

9. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 9 of the Complaint, except admits that the Court's January 8, 2014 Order stated that "on October 30, 2014, the states of California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, and Wisconsin (the 'Intervening States') filed a notice with the Court, indicating that they were intervening against Novartis as to the relator's allegations concerning the Novartis drug Exjade."

10. Because numbered paragraph 10 of the Complaint states conclusions or characterizations of law, no response is required.

11. Denies the allegations set forth in numbered paragraph 11 of the Complaint, except admits that Novartis markets and sells brand name prescription medications within the geographic boundaries over which the United States District Court for the Southern District of New York presides. To the extent that numbered paragraph 11 of the Complaint states conclusions or characterizations of law, no response is required.

12. Admits the allegations set forth in numbered paragraph 12 of the Complaint.

13. Admits the allegations set forth in numbered paragraph 13 of the Complaint.

14. Admits the allegations set forth in numbered paragraph 14 of the Complaint.

15. Admits the allegations set forth in numbered paragraph 15 of the Complaint.

16. Admits the allegations set forth in numbered paragraph 16 of the Complaint.

17. Admits the allegations set forth in numbered paragraph 17 of the Complaint.

18. Admits the allegations set forth in numbered paragraph 18 of the Complaint.

19. Admits the allegations set forth in numbered paragraph 19 of the Complaint.

20. Admits the allegations set forth in numbered paragraph 20 of the Complaint.

21. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 21 of the Complaint.

22. Denies the allegations set forth in numbered paragraph 22, except admits that Novartis is an indirect subsidiary of Novartis AG, a Swiss public company, and admits that Novartis is headquartered in East Hanover, New Jersey and markets and sells brand name prescription medications in California and within the geographic boundaries over which the United States District Court for the Southern District of New York presides.

23. Because numbered paragraph 23 of the Complaint states conclusions or characterizations of law, no response is required.

24. Admits that the AKS contains the language quoted in numbered paragraph 24 of the Complaint and respectfully refers the Court to 42 U.S.C. § 1320a-7b for the entire text. To the extent that numbered paragraph 24 of the Complaint states conclusions or characterizations of law, no response is required.

25. Admits that the AKS contains the language quoted in numbered paragraph 25 of the Complaint and respectfully refers the Court to 42 U.S.C. § 1320a-7b for the entire text, and admits that the PPACA was not enacted until 2010. To the extent that numbered paragraph 25 of the Complaint states conclusions or characterizations of law, no response is required.

26. Because numbered paragraph 26 of the Complaint states conclusions or characterizations of law, no response is required.

27. Because numbered paragraph 27 of the Complaint states conclusions or characterizations of law, no response is required.

28. Admits that the “Special Fraud Alerts” contain the language quoted in numbered paragraph 28 of the Complaint and respectfully refers the Court to the Federal Register for the entire text. To the extent that numbered paragraph 28 of the Complaint states conclusions or characterizations of law, no response is required.

29. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 29 of the Complaint. To the extent that numbered paragraph 29 of the Complaint states conclusions or characterizations of law, no response is required.

30. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 30 of the Complaint. To the extent that numbered paragraph 30 of the Complaint states conclusions or characterizations of law, no response is required.

31. Admits that N.Y. State Fin. Law § 189(1) contains the language quoted in numbered paragraph 31 of the Complaint, and respectfully refers the Court to that statute for the entire text. To the extent that numbered paragraph 31 of the Complaint states conclusions or characterizations of law, no response is required.

32. Admits that N.Y. State Fin. Law § 188(3) contains the language quoted in numbered paragraph 32 of the Complaint, and respectfully refers the Court to that statute for the entire text. To the extent that numbered paragraph 32 of the Complaint states conclusions or characterizations of law, no response is required.

33. Admits that N.Y. State Fin. Law § 188(1) contains the language quoted in numbered paragraph 33 of the Complaint, and respectfully refers the Court to that statute for the

entire text. To the extent that numbered paragraph 33 of the Complaint states conclusions or characterizations of law, no response is required.

34. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 34 of the Complaint. To the extent that numbered paragraph 34 of the Complaint states conclusions or characterizations of law, no response is required.

35. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 35 of the Complaint, except admits that Medicaid is a joint federal-state program, and respectfully refers the Court to the relevant federal and state statutes and regulations for a description of the program. To the extent that numbered paragraph 35 of the Complaint states conclusions or characterizations of law, no response is required.

36. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 36 of the Complaint. To the extent that numbered paragraph 36 of the Complaint states conclusions or characterizations of law, no response is required.

37. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 37 of the Complaint. To the extent that numbered paragraph 37 of the Complaint states conclusions or characterizations of law, no response is required.

38. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 38 of the Complaint. To the extent that numbered paragraph 38 of the Complaint states conclusions or characterizations of law, no response is required.

39. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 39 of the Complaint. To the extent that numbered paragraph 39 of the Complaint states conclusions or characterizations of law, no response is required.

40. Admits Georgia's Medicaid Manual contains the language quoted in numbered paragraph 40 of the Complaint, and respectfully refers the Court to that Manual for the entire text. To the extent that numbered paragraph 40 of the Complaint states conclusions or characterizations of law, no response is required.

41. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 41 of the Complaint. To the extent that numbered paragraph 41 of the Complaint states conclusions or characterizations of law, no response is required.

42. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 42 of the Complaint. To the extent that numbered paragraph 42 of the Complaint states conclusions or characterizations of law, no response is required.

43. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 43 of the Complaint. To the extent that numbered paragraph 43 of the Complaint states conclusions or characterizations of law, no response is required.

44. Because the allegations set forth in numbered paragraph 44 of the Complaint state conclusions or characterizations of law, no response is required.

45. Because the allegations set forth in numbered paragraph 45 of the Complaint state conclusions or characterizations of law, no response is required.

46. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 46 of the Complaint. To the extent that numbered paragraph 46 of the Complaint states conclusions or characterizations of law, no response is required.

47. Because the allegations set forth in numbered paragraph 47 of the Complaint state conclusions or characterizations of law, no response is required.

48. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 48 of the Complaint. To the extent that numbered paragraph 48 of the Complaint states conclusions or characterizations of law, no response is required.

49. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 49 of the Complaint. To the extent that numbered paragraph 49 of the Complaint states conclusions or characterizations of law, no response is required.

50. Because the allegations set forth in numbered paragraph 50 of the Complaint state conclusions or characterizations of law, no response is required.

51. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 51 of the Complaint. To the extent that numbered paragraph 51 of the Complaint states conclusions or characterizations of law, no response is required.

52. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 52 of the Complaint. To the extent that numbered paragraph 52 of the Complaint states conclusions or characterizations of law, no response is required.

53. Because the allegations set forth in numbered paragraph 53 of the Complaint state conclusions or characterizations of law, no response is required.

54. Because the allegations set forth in numbered paragraph 54 of the Complaint state conclusions or characterizations of law, no response is required.

55. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 55 of the Complaint. To the extent that numbered paragraph 55 of the Complaint states conclusions or characterizations of law, no response is required.

56. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 56 of the Complaint. To the extent that numbered paragraph 56 of the Complaint states conclusions or characterizations of law, no response is required.

57. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 57 of the Complaint. To the extent that numbered paragraph 57 of the Complaint states conclusions or characterizations of law, no response is required.

58. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 58 of the Complaint. To the extent that numbered

paragraph 58 of the Complaint states conclusions or characterizations of law, no response is required.

59. Because the allegations set forth in numbered paragraph 59 of the Complaint state conclusions or characterizations of law, no response is required.

60. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 60 of the Complaint. To the extent that numbered paragraph 60 of the Complaint states conclusions or characterizations of law, no response is required.

61. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 61 of the Complaint. To the extent that numbered paragraph 61 of the Complaint states conclusions or characterizations of law, no response is required.

62. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 62 of the Complaint. To the extent that numbered paragraph 62 of the Complaint states conclusions or characterizations of law, no response is required.

63. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 63 of the Complaint. To the extent that numbered paragraph 63 of the Complaint states conclusions or characterizations of law, no response is required.

64. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 64 of the Complaint.

65. Denies the allegations set forth in numbered paragraph 65 of the Complaint.

66. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 66 of the Complaint.

67. Denies the allegations set forth in numbered paragraph 67 of the Complaint.

68. Admits that there exists Novartis Pharma Principles & Practices for Professionals that contains the language quoted in numbered paragraph 68, and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 68 of the Complaint.

69. Admits that Novartis Ethics and Compliance (“E&C”) Policies contain the language quoted in numbered paragraph 69 and respectfully refers the Court to that document for a full and complete reading of its content.

70. Admits that Novartis’s internal policies include Novartis E&C Policies that contain the language quoted in numbered paragraph 70 and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 70 of the Complaint.

71. Admits that Novartis E&C Policies contain the language quoted in numbered paragraph 71 and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 71 of the Complaint.

72. Admits that Novartis E&C Policies contain the language quoted in numbered paragraph 72 and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 72 of the Complaint.

73. Admits that Novartis has fully complied with the AKS and its own internal policies in connection with the sale, promotion and marketing of Exjade, and is further unable to respond because the allegation in numbered paragraph 73 lacks any information about the identities of the referenced executives.

74. Admits that, in September 2010, Novartis entered into a settlement agreement with the Government and several Relators to resolve civil claims brought by the Government, the Relators and certain states regarding Novartis's promotion of certain drugs and that Novartis entered into a separate plea agreement with the Government with respect to any information brought by the Government regarding Novartis's alleged off label promotion of one drug, and respectfully refers the Court to those documents for a full and complete reading of their content, and denies the remaining allegations set forth in numbered paragraph 74 of the Complaint.

75. Admits the allegations set forth in numbered paragraph 75 of the Complaint, and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content.

76. Admits that the Novartis CIA contains the language quoted in numbered paragraph 76 of the Complaint and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content.

77. Admits that the Novartis CIA contains various certification provisions and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 77 of the Complaint.

78. Admits that the Novartis CIA contains various notification provisions and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 78 of the Complaint.

79. Admits the allegations set forth in numbered paragraph 79 of the Complaint, and respectfully refers the Court to the 2005 Exjade label for a full and complete reading of its content.

80. Denies the first sentence of numbered paragraph 80 of the Complaint, except admits that the FDA approved Exjade under 21 C.F.R. § 314.510, and respectfully refers the Court to that provision for a full and complete reading of its content. Because the second and third sentences of numbered paragraph 80 of the Complaint state conclusions or characterizations of law, no response is required.

81. Admits the allegation set forth in the first sentence of numbered paragraph 81 of the Complaint. Denies the second sentence of numbered paragraph 81 of the Complaint, except admits that Exjade is prescribed for patients with beta-thalassemia, sickle cell disease and myelodysplastic syndrome.

82. Denies the allegations set forth in numbered paragraph 82 of the Complaint.

83. Denies the allegations set forth in numbered paragraph 83 of the Complaint, and respectfully refers the Court to the 2005 Exjade label for a full and complete reading of its content.

84. Denies the allegations set forth in numbered paragraph 84 of the Complaint.

85. Denies the allegations set forth in numbered paragraph 85 of the Complaint, except admits that text regarding warnings and precautions was added to the Exjade labels, and respectfully refers the Court to the Exjade labels referenced in the Complaint for a full and complete reading of their content.

86. Denies the allegations set forth in numbered paragraph 86 of the Complaint, but admits that the 2010 version of the Exjade label contains a boxed warning, and respectfully

refers the Court to that warning for a full and complete reading of its content. Because footnote number 1 in numbered paragraph 86 of the Complaint states conclusions or characterizations of law, no response is required.

87. Denies the allegations set forth in numbered paragraph 87, but admits that Novartis submitted responses to the FDA on July 8, 2009 and October 14, 2009, and respectfully refers the Court to those responses.

88. Denies the allegations set forth in numbered paragraph 88, except admits that the 2010 Exjade label contains a boxed warning, and respectfully refers the Court to the language of the boxed warning in the January 2010 Exjade label for a full and complete reading of its content.

89. Denies the allegations set forth in numbered paragraph 89 of the Complaint, except admits EPASS was a distribution network that included three pharmacies that dispensed Exjade.

90. Denies the allegations set forth in numbered paragraph 90 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

91. Denies the allegations set forth in numbered paragraph 91 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

92. Denies the allegations set forth in numbered paragraph 92 and footnote 2 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

93. Denies the allegations set forth in numbered paragraph 93 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

94. Denies the allegations set forth in numbered paragraph 94 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

95. Denies the allegations set forth in numbered paragraph 95 of the Complaint.

96. Denies the allegations set forth in numbered paragraph 96 of the Complaint.

97. Denies the allegations set forth in numbered paragraph 97 of the Complaint.

98. Denies the allegations set forth in numbered paragraph 98 and footnote 3 of the Complaint.

99. Denies the allegations set forth in numbered paragraph 99 of the Complaint.

100. Denies the allegations set forth in numbered paragraph 100 of the Complaint.

101. Denies the allegations set forth in numbered paragraph 101 of the Complaint.

102. Denies the allegations set forth in numbered paragraph 102 of the Complaint.

103. Denies the allegations set forth in numbered paragraph 103 of the Complaint.

104. Denies the allegations set forth in numbered paragraph 104 of the Complaint.

105. Denies the allegations set forth in numbered paragraph 105 of the Complaint.

106. Denies the allegations set forth in numbered paragraph 106 of the Complaint.

107. Denies the allegations set forth in numbered paragraph 107 of the Complaint.

108. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 108 of the Complaint.

109. Denies the allegations set forth in numbered paragraph 109 of the Complaint.

110. Denies the allegations set forth in numbered paragraph 110 of the Complaint.

111. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 111 of the Complaint.

112. Denies the allegations set forth in numbered paragraph 112 of the Complaint.

113. Denies the allegations set forth in numbered paragraph 113 of the Complaint.

114. Denies the allegations set forth in numbered paragraph 114 of the Complaint.

115. Denies the allegations set forth in numbered paragraph 115 of the Complaint.

116. Denies the allegations set forth in numbered paragraph 116 of the Complaint.

117. Denies the allegations set forth in numbered paragraph 117 of the Complaint.

118. Denies the allegations set forth in numbered paragraph 118 of the Complaint.

119. Denies the allegations set forth in numbered paragraph 119 of the Complaint, except admits that a contractual amendment was executed in June 2008, and respectfully refers the Court to that amendment.

120. Denies the allegations set forth in numbered paragraph 120 of the Complaint.

121. Denies the allegations set forth in numbered paragraph 121 of the Complaint.

122. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 122 of the Complaint.

123. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 123 of the Complaint.

124. Denies the allegations set forth in numbered paragraph 124 of the Complaint.

125. Denies the allegations set forth in numbered paragraph 125 of the Complaint.

126. Denies the allegations set forth in numbered paragraph 126 of the Complaint.

127. Denies the allegations set forth in numbered paragraph 127 of the Complaint.

128. Denies the allegations set forth in numbered paragraph 128 of the Complaint.

129. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 129 of the Complaint.

130. Denies the allegations set forth in the first sentence of numbered paragraph 130 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second, third and fourth sentences of numbered paragraph 130 of the Complaint.

131. Denies the allegations set forth in numbered paragraph 131 of the Complaint.

132. Denies the allegations set forth in numbered paragraph 132 of the Complaint.

133. Denies the allegations set forth in numbered paragraph 133 of the Complaint.

134. Denies the allegations set forth in numbered paragraph 134 of the Complaint.

135. Denies the allegations set forth in numbered paragraph 135 of the Complaint.

136. Denies the allegations set forth in the first and third sentences of numbered paragraph 136 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 136 of the Complaint.

137. Denies the allegations set forth in numbered paragraph 137 of the Complaint.

138. Denies the allegations set forth in numbered paragraph 138 of the Complaint.

139. Denies the allegations set forth in the first, second, third and fourth sentences of numbered paragraph 139 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the fifth sentence of numbered paragraph 139 of the complaint.

140. Denies the allegations set forth in numbered paragraph 140 of the Complaint, except admits that the 2010 version of the Exjade label contains a boxed warning, and respectfully refers the Court to that warning for a full and complete reading of its content.

141. Denies the allegations set forth in numbered paragraph 141, except admits that Novartis submitted responses to the FDA on July 8, 2009 and October 14, 2009, and respectfully refers the Court to those responses.

142. Denies the allegations set forth in the first sentence of numbered paragraph 142 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 142 of the Complaint.

143. Denies the allegations set forth in numbered paragraph 143 of the Complaint, and respectfully refers the Court to the cited deposition for a full and complete reading of its content.

144. Denies the allegations set forth in numbered paragraph 144 and footnote 4 of the Complaint, and respectfully refers the Court to the cited deposition for a full and complete reading of its content.

145. Denies the allegations set forth in numbered paragraph 145 of the Complaint.

146. Denies the allegations set forth in numbered paragraph 146 of the Complaint, except admits that Novartis had a contractual relationship with BioScrip since 2005, and respectfully refers the Court to those contracts.

147. Denies the allegations set forth in numbered paragraph 147 of the Complaint.

148. Denies the allegations set forth in numbered paragraph 148 of the Complaint.

149. Denies the allegations set forth in numbered paragraph 149 of the Complaint.

150. Denies the allegations set forth in numbered paragraph 150 of the Complaint.

151. Denies the allegations set forth in numbered paragraph 151 of the Complaint, and respectfully refers the Court to the referenced contracts.

152. Denies the allegations set forth in numbered paragraph 152 of the Complaint.

153. Denies the allegations set forth in numbered paragraph 153 of the Complaint.

154. Denies the allegations set forth in numbered paragraph 154 of the Complaint.

155. Denies the allegations set forth in numbered paragraph 155 of the Complaint. To the extent that numbered paragraph 155 of the Complaint states conclusions or characterizations of law, no response is required.

156. Denies the allegations set forth in numbered paragraph 156 of the Complaint. To the extent that numbered paragraph 156 of the Complaint states conclusions or characterizations of law, no response is required.

157. Denies the allegations set forth in numbered paragraph 157 of the Complaint.

158. Denies the allegations set forth in numbered paragraph 158 of the Complaint.

CLAIMS OF THE STATE OF GEORGIA

COUNT ONE *FALSE CLAIM*

Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*

159. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

160. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 160 of the Complaint.

161. Denies the allegations set forth in numbered paragraph 161 of the Complaint.

162. Denies the allegations set forth in numbered paragraph 162 of the Complaint.

COUNT TWO *FALSE RECORD*

Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*

163. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

164. Denies the allegations set forth in numbered paragraph 164 of the Complaint.

165. Denies the allegations set forth in numbered paragraph 165 of the Complaint.

COUNT THREE *CONSPIRACY*

Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*

166. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

167. Denies the allegations set forth in numbered paragraph 167 of the Complaint.

168. Denies the allegations set forth in numbered paragraph 168 of the Complaint.

**COUNT FOUR
Unjust Enrichment**

169. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

170. Denies the allegations set forth in numbered paragraph 170 of the Complaint.

171. Denies the allegations set forth in numbered paragraph 171 of the Complaint.

CLAIMS OF THE STATE OF ILLINOIS

COUNT FIVE *FALSE CLAIM*

Illinois False Claims Act, 740 ILCS 175/3(a)(1)(A)

172. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

173. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 173 of the Complaint.

174. Denies the allegations set forth in numbered paragraph 174 of the Complaint.

175. Denies the allegations set forth in numbered paragraph 175 of the Complaint.

COUNT SIX *FALSE RECORD*
Illinois False Claims Act, 740 ILCS 175/3(a)(1)(B)

176. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

177. Denies the allegations set forth in numbered paragraph 177 of the Complaint.

178. Denies the allegations set forth in numbered paragraph 178 of the Complaint.

COUNT SEVEN *CONSPIRACY*
Illinois False Claims Act, 740 ILCS 175/3(a)(1)(C)

179. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

180. Denies the allegations set forth in numbered paragraph 180 of the Complaint.

181. Denies the allegations set forth in numbered paragraph 181 of the Complaint.

COUNT EIGHT *MEDICAID FALSE STATEMENT*
Illinois False Claims Act, 740 ILCS 175/3(a)(1)(B)

182. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

183. Denies the allegations set forth in numbered paragraph 183 of the Complaint.

184. Denies the allegations set forth in numbered paragraph 184 of the Complaint.

185. Denies the allegations set forth in numbered paragraph 185 of the Complaint.

186. Denies the allegations set forth in numbered paragraph 186 of the Complaint.

COUNT NINE *FRAUDULENT ACTS*
Public Assistance Fraud, 305 ILCS 5/8A-7

187. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

188. Admits that 305 ILCS 5/8A-7 contains the language quoted in numbered paragraph 188 of the Complaint, and respectfully refers the Court to that statute for the entire text. To the extent that numbered paragraph 188 of the Complaint states conclusions or characterizations of law, no response is required.

189. Denies the allegations set forth in numbered paragraph 189 of the Complaint

190. Denies the allegations set forth in numbered paragraph 190 of the Complaint.

**COUNT TEN
Unjust Enrichment**

191. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

192. Denies the allegations set forth in numbered paragraph 192 of the Complaint.

193. Denies the allegations set forth in numbered paragraph 193 of the Complaint.

CLAIMS OF THE STATE OF INDIANA

COUNT ELEVEN *FALSE CLAIM*

Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*

194. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

195. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 195 of the Complaint.

196. Denies the allegations set forth in numbered paragraph 196 of the Complaint.

197. Denies the allegations set forth in numbered paragraph 197 of the Complaint.

COUNT TWELVE *FALSE RECORD*

Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*

198. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

199. Denies the allegations set forth in numbered paragraph 199 of the Complaint.

200. Denies the allegations set forth in numbered paragraph 200 of the Complaint.

COUNT THIRTEEN *CONSPIRACY*
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*

201. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

202. Denies the allegations set forth in numbered paragraph 202 of the Complaint.

203. Denies the allegations set forth in numbered paragraph 203 of the Complaint.

COUNT FOURTEEN *MEDICAID FRAUD*
Indiana Code § 35-43-5-7.1

204. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

205. Admits that Ind. Code § 35-43-5-7.1 contains the language quoted in numbered paragraph 205 of the Complaint, and respectfully refers the Court to that statute for the entire text. To the extent that numbered paragraph 205 of the Complaint states conclusions or characterizations of law, no response is required.

206. Because the allegations set forth in numbered paragraph 206 of the Complaint state conclusions or characterizations of law, no response is required.

207. Denies the allegations set forth in numbered paragraph 207 of the Complaint.

208. Denies the allegations set forth in numbered paragraph 208 of the Complaint.

209. Denies the allegations set forth in numbered paragraph 209 of the Complaint.

COUNT FIFTEEN *THEFT*
Indiana Code § 35-43-4-2

210. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

211. Admits that Ind. Code § 12-15-24-2 contains the language quoted in numbered paragraph 211 of the Complaint, and respectfully refers the Court to that statute for the entire text. To the extent that numbered paragraph 211 of the Complaint states conclusions or characterizations of law, no response is required.

212. Denies the allegations set forth in numbered paragraph 212 of the Complaint.

213. Denies the allegations set forth in numbered paragraph 213 of the Complaint.

214. Admits that Ind. Code § 12-15-24-1 contains the language quoted in numbered paragraph 214 of the Complaint, and respectfully refers the Court to that statute for the entire text. To the extent that numbered paragraph 214 of the Complaint states conclusions or characterizations of law, no response is required.

215. Denies the allegations set forth in numbered paragraph 215 of the Complaint.

216. Admits that Ind. Code § 35-43-4-2(a), Ind. Code § 35-43-4-1(a) and Ind. Code § 35-43-4-1(b) contain the language quoted in numbered paragraph 216 of the Complaint, and respectfully refers the Court to that statute for the entire text. To the extent that numbered paragraph 216 of the Complaint states conclusions or characterizations of law, no response is required.

217. Because the allegations set forth in numbered paragraph 217 of the Complaint state conclusions or characterizations of law, no response is required.

218. Denies the allegations set forth in numbered paragraph 218 of the Complaint.

219. Denies the allegations set forth in numbered paragraph 219 of the Complaint.

COUNT SIXTEEN
Unjust Enrichment

220. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

221. Denies the allegations set forth in numbered paragraph 221 of the Complaint.

222. Denies the allegations set forth in numbered paragraph 222 of the Complaint.

CLAIMS OF THE STATE OF MARYLAND

COUNT SEVENTEEN *FALSE CLAIM*

Maryland False Claims Act, Md. Code, Health-Gen. §§ 2-601 through 2-611

223. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

224. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 224 of the Complaint.

225. Denies the allegations set forth in numbered paragraph 225 of the Complaint.

226. Denies the allegations set forth in numbered paragraph 226 of the Complaint.

COUNT EIGHTEEN *FALSE RECORD*

Maryland False Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 through 2-611

227. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

228. Denies the allegations set forth in numbered paragraph 228 of the Complaint.

229. Denies the allegations set forth in numbered paragraph 229 of the Complaint.

COUNT NINETEEN *CONSPIRACY*

Maryland False Claims Act, Md. Code, Health-Gen. §§ 2-601 through 2-611

230. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

231. Denies the allegations set forth in numbered paragraph 231 of the Complaint.

232. Denies the allegations set forth in numbered paragraph 232 of the Complaint.

COUNT TWENTY *MEDICAID FALSE STATEMENT*
Maryland False Claims Act, Md. Code, Health-Gen. §§ 2-601 through 2-611

233. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

234. Denies the allegations set forth in numbered paragraph 234 of the Complaint.

235. Denies the allegations set forth in numbered paragraph 235 of the Complaint.

236. Denies the allegations set forth in numbered paragraph 236 of the Complaint.

237. Denies the allegations set forth in numbered paragraph 237 of the Complaint.

COUNT TWENTY-ONE
Intentional Misrepresentation
(Fraud)

238. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

239. Denies the allegations set forth in numbered paragraph 239 of the Complaint.

240. Denies the allegations set forth in numbered paragraph 240 of the Complaint.

241. Denies the allegations set forth in numbered paragraph 241 of the Complaint.

242. Denies the allegations set forth in numbered paragraph 242 of the Complaint.

243. Denies the allegations set forth in numbered paragraph 243 of the Complaint.

COUNT TWENTY-TWO
Constructive Fraud

244. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

245. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 245 of the Complaint. To the extent that numbered paragraph 245 of the Complaint states conclusions or characterizations of law, no response is required.

246. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 246 of the Complaint. To the extent that numbered paragraph 246 of the Complaint states conclusions or characterizations of law, no response is required.

247. Denies the allegations set forth in numbered paragraph 247 of the Complaint.

248. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 248 of the Complaint. To the extent that numbered paragraph 248 of the Complaint states conclusions or characterizations of law, no response is required.

249. Denies the allegations set forth in numbered paragraph 249 of the Complaint.

250. Denies the allegations set forth in numbered paragraph 250 of the Complaint.

251. Denies the allegations set forth in numbered paragraph 251 of the Complaint.

COUNT TWENTY-THREE
Unjust Enrichment

252. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

253. Denies the allegations set forth in numbered paragraph 253 of the Complaint.

254. Denies the allegations set forth in numbered paragraph 254 of the Complaint.

255. Denies the allegations set forth in numbered paragraph 255 of the Complaint.

256. Denies the allegations set forth in numbered paragraph 256 of the Complaint.

257. Denies the allegations set forth in numbered paragraph 257 of the Complaint.

258. Denies the allegations set forth in numbered paragraph 258 of the Complaint.

CLAIMS OF THE STATE OF MICHIGAN

**COUNT TWENTY-FOUR *KICKBACK*
Michigan Medicaid False Claims Act, MCL 400.604**

259. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

260. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 260 of the Complaint.

261. Denies the allegations set forth in numbered paragraph 261 of the Complaint.

262. Denies the allegations set forth in numbered paragraph 262 of the Complaint.

263. Denies the allegations set forth in numbered paragraph 263 of the Complaint.

**COUNT TWENTY-FIVE *FALSE CLAIM*
Michigan Medicaid False Claims Act, MCL 400.607(1)**

264. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

265. Denies the allegations set forth in numbered paragraph 265 of the Complaint.

266. Denies the allegations set forth in numbered paragraph 266 of the Complaint.

**COUNT TWENTY-SIX *FALSE RECORD*
Michigan Medicaid False Claims Act, MCL 400.607(3)**

267. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

268. Denies the allegations set forth in numbered paragraph 268 of the Complaint.

269. Denies the allegations set forth in numbered paragraph 269 of the Complaint.

**COUNT TWENTY-SEVEN *CONSPIRACY*
Michigan Medicaid False Claims Act, MCL 400.606**

270. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

271. Denies the allegations set forth in numbered paragraph 271 of the Complaint.

272. Denies the allegations set forth in numbered paragraph 272 of the Complaint.

COUNT TWENTY-EIGHT
Common Law Fraud

273. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

274. Denies the allegations set forth in numbered paragraph 274 of the Complaint.

275. Denies the allegations set forth in numbered paragraph 275 of the Complaint.

COUNT TWENTY-NINE
Unjust Enrichment

276. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

277. Denies the allegations set forth in numbered paragraph 277 of the Complaint.

278. Denies the allegations set forth in numbered paragraph 278 of the Complaint.

279. Denies the allegations set forth in numbered paragraph 279 of the Complaint.

CLAIMS OF THE STATE OF NEW JERSEY

COUNT THIRTY *FALSE CLAIM*
New Jersey False Claims Act, N.J.S.A. 32C-1, *et seq.*

280. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

281. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 281 of the Complaint.

282. Denies the allegations set forth in numbered paragraph 282 of the Complaint.

283. Denies the allegations set forth in numbered paragraph 283 of the Complaint.

COUNT THIRTY-ONE *FALSE RECORD*
New Jersey False Claims Act, N.J.S.A. 2A:32C-3b

284. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

285. Denies the allegations set forth in numbered paragraph 285 of the Complaint.

286. Denies the allegations set forth in numbered paragraph 286 of the Complaint.

COUNT THIRTY-TWO *CONSPIRACY*
New Jersey False Claims Act, N.J.S.A. 2A:32C-3c

287. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

288. Denies the allegations set forth in numbered paragraph 288 of the Complaint.

289. Denies the allegations set forth in numbered paragraph 289 of the Complaint.

COUNT THIRTY-THREE *MEDICAID FALSE STATEMENT*
N.J.S.A. § 30:4D-17(b)

290. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

291. Denies the allegations set forth in numbered paragraph 291 of the Complaint.

292. Denies the allegations set forth in numbered paragraph 292 of the Complaint.

293. Denies the allegations set forth in numbered paragraph 293 of the Complaint.

294. Denies the allegations set forth in numbered paragraph 294 of the Complaint.

COUNT THIRTY-FOUR *CONVERSION*
Conversion

295. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

296. Denies the allegations set forth in numbered paragraph 296 of the Complaint.

297. Denies the allegations set forth in numbered paragraph 297 of the Complaint.

298. Denies the allegations set forth in numbered paragraph 298 of the Complaint.

**COUNT THIRTY-FIVE
Common Law Fraud**

299. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

300. Denies the allegations set forth in numbered paragraph 300 of the Complaint.

301. Denies the allegations set forth in numbered paragraph 301 of the Complaint.

302. Denies the allegations set forth in numbered paragraph 302 of the Complaint.

**COUNT THIRTY-SIX
Unjust Enrichment**

303. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

304. Denies the allegations set forth in numbered paragraph 304 of the Complaint.

305. Denies the allegations set forth in numbered paragraph 305 of the Complaint.

CLAIMS OF THE STATE OF NEW YORK

**COUNT THIRTY-SEVEN *FALSE CLAIM*
New York False Claims Act, N.Y. State Fin. Law § 189(1)(a)**

306. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

307. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 307 of the Complaint.

308. Denies the allegations set forth in numbered paragraph 308 of the Complaint.

309. Denies the allegations set forth in numbered paragraph 309 of the Complaint.

COUNT THIRTY-EIGHT *FALSE RECORD*
New York False Claims Act, N.Y. State Fin. Law § 189(1)(b)

310. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

311. Denies the allegations set forth in numbered paragraph 311 of the Complaint.

312. Denies the allegations set forth in numbered paragraph 312 of the Complaint.

COUNT THIRTY-NINE *CONSPIRACY*
New York False Claims Act, N.Y. State Fin. Law § 189(1)(c)

313. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

314. Denies the allegations set forth in numbered paragraph 314 of the Complaint.

315. Denies the allegations set forth in numbered paragraph 315 of the Complaint.

COUNT FORTY *FALSE STATEMENT*
New York Social Services Law § 145-b

316. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

317. Denies the allegations set forth in numbered paragraph 317 of the Complaint.

318. Denies the allegations set forth in numbered paragraph 318 of the Complaint.

319. Denies the allegations set forth in numbered paragraph 319 of the Complaint.

320. Denies the allegations set forth in numbered paragraph 320 of the Complaint.

COUNT FORTY-ONE *REPEATED FRAUDULENT ACTS*
New York Executive Law § 63(12)

321. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

322. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 322 of the Complaint. To the extent that numbered

paragraph 322 of the Complaint states conclusions or characterizations of law, no response is required.

323. Denies the allegations set forth in numbered paragraph 323 of the Complaint.

324. Denies the allegations set forth in numbered paragraph 324 of the Complaint.

COUNT FORTY-TWO *MISAPPROPRIATION OF PUBLIC PROPERTY*
New York Executive Law § 63-c

325. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

326. Denies the allegations set forth in numbered paragraph 326 of the Complaint.

COUNT FORTY-THREE
Unjust Enrichment

327. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

328. Denies the allegations set forth in numbered paragraph 328 of the Complaint.

329. Denies the allegations set forth in numbered paragraph 329 of the Complaint.

CLAIMS OF THE STATE OF OKLAHOMA

COUNT FORTY-FOUR *KICKBACKS*
Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56, §§ 1005-1007

330. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

331. Denies the allegations set forth in numbered paragraph 331 of the Complaint.

332. Denies the allegations set forth in numbered paragraph 332 of the Complaint.

COUNT FORTY-FIVE *FALSE CLAIM*
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1

333. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

334. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 334 of the Complaint

335. Denies the allegations set forth in numbered paragraph 335 of the Complaint.

336. Denies the allegations set forth in numbered paragraph 336 of the Complaint.

COUNT FORTY-SIX *FALSE RECORD OR STATEMENT*
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1

337. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

338. Denies the allegations set forth in numbered paragraph 338 of the Complaint.

339. Denies the allegations set forth in numbered paragraph 339 of the Complaint.

COUNT FORTY-SEVEN *CONSPIRACY*
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1

340. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

341. Denies the allegations set forth in numbered paragraph 341 of the Complaint.

342. Denies the allegations set forth in numbered paragraph 342 of the Complaint.

COUNT FORTY-EIGHT *MEDICAID PROGRAM INTEGRITY VIOLATION*
Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56, §§ 1005-1007

343. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

344. Denies the allegations set forth in numbered paragraph 344 of the Complaint.

345. Denies the allegations set forth in numbered paragraph 345 of the Complaint.

COUNT FORTY-NINE *FRAUD*
Common Law Fraud

346. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

347. Denies the allegations set forth in numbered paragraph 347 of the Complaint.

348. Denies the allegations set forth in numbered paragraph 348 of the Complaint.

349. Denies the allegations set forth in numbered paragraph 349 of the Complaint.

COUNT FIFTY
Civil Conspiracy

350. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

351. Denies the allegations set forth in numbered paragraph 351 of the Complaint.

352. Denies the allegations set forth in numbered paragraph 352 of the Complaint.

COUNT FIFTY-ONE
Unjust Enrichment

353. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

354. Denies the allegations set forth in numbered paragraph 354 of the Complaint.

355. Denies the allegations set forth in numbered paragraph 355 of the Complaint.

CLAIMS OF THE STATE OF WISCONSIN

COUNT FIFTY-TWO
Wisconsin False Claims For Medical Assistance Law, Wis. Stat. § 20.931(2)(a)
(Medical Assistance Fraud)

356. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

357. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 357 of the Complaint.

358. Denies the allegations set forth in numbered paragraph 358 of the Complaint.

359. Denies the allegations set forth in numbered paragraph 359 of the Complaint.

COUNT FIFTY-THREE

**Wisconsin False Claims For Medical Assistance Law, Wis. Stat. § 20.931(2)(b)
(False Record)**

360. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

361. Denies the allegations set forth in numbered paragraph 361 of the Complaint.

362. Denies the allegations set forth in numbered paragraph 362 of the Complaint.

COUNT FIFTY-FOUR

**Wisconsin False Claims For Medical Assistance Law, Wis. Stat. § 20.931(2)(c)
(Conspiracy)**

363. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

364. Denies the allegations set forth in numbered paragraph 364 of the Complaint.

365. Denies the allegations set forth in numbered paragraph 365 of the Complaint.

COUNT FIFTY-FIVE

Unjust Enrichment

366. Novartis repeats and incorporates by reference its responses to each of the preceding paragraphs set forth herein.

367. Denies the allegations set forth in numbered paragraph 367 of the Complaint.

368. Denies the allegations set forth in numbered paragraph 368 of the Complaint.

369. Denies the allegations set forth in numbered paragraph 369 of the Complaint.

370. Denies the allegations set forth in numbered paragraph 370 of the Complaint.

371. Denies the allegations set forth in numbered paragraph 371 of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The States fail to state a claim against Novartis upon which relief may be granted, and the Complaint should be dismissed.

SECOND AFFIRMATIVE DEFENSE

The States fail to allege any false claim under the Federal or relevant state False Claims Acts because Novartis's conduct did not result in any "false or fraudulent claim" in violation of 31 U.S.C. § 3729(a) or any State equivalents.

THIRD AFFIRMATIVE DEFENSE

The States fail to allege that any claim submitted by a pharmacy prior to March 2010 was a false or fraudulent claim under the Federal or relevant state False Claims Acts because those claims did not contain express or implied statements that were false or fraudulent as a result of the conduct alleged against Novartis.

FOURTH AFFIRMATIVE DEFENSE

The States' claims fail because the rebate payments, discounts and the patient allocations at issue are not unlawful kickbacks under 42 U.S.C. § 1320a-7b or any State equivalents.

FIFTH AFFIRMATIVE DEFENSE

The States' claims fail because the rebate payments and discounts at issue are protected under the statutory exception for discounts provided for in 42 U.S.C. § 1320a-7b(b)(3)(A) and any State equivalents.

SIXTH AFFIRMATIVE DEFENSE

The States' claims fail because the rebate payments and discounts at issue are protected under the regulatory exceptions (safe harbors) for discounts provided for in 42 C.F.R. § 1001.952(h) and any State equivalents.

SEVENTH AFFIRMATIVE DEFENSE

The States' claims are barred because, at all times relevant hereto, Novartis complied with all applicable federal and state regulations.

EIGHTH AFFIRMATIVE DEFENSE

The States' claims are barred, in whole or in part, because they rely upon ambiguous provisions of the Federal and state False Claims Acts and other provisions of law, and the rule of lenity requires such ambiguities to be construed in Novartis's favor.

NINTH AFFIRMATIVE DEFENSE

The States' claims are barred, in whole or in part, because they violate Novartis's rights under the Due Process and Ex Post Facto clauses of the United States Constitution and the Constitutions of the States, insofar as the States seek to impose liability retroactively for conduct that is not prohibited by federal statutes or regulations.

TENTH AFFIRMATIVE DEFENSE

The States' claims fail because any and all actions taken by Novartis with respect to any of the matters alleged in the Complaint were taken in accordance with established industry practice.

ELEVENTH AFFIRMATIVE DEFENSE

The States' claims are barred, in whole or in part, due to its failure to join indispensable parties.

TWELFTH AFFIRMATIVE DEFENSE

The States' claims are barred, in whole or in part, by the applicable statutes of limitations and repose.

THIRTEENTH AFFIRMATIVE DEFENSE

The States' claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that the States, through the Medicaid program, have reimbursed specialty pharmacy providers for dispensing Exjade to Medicaid beneficiaries after the filing of the Complaint.

FOURTEENTH AFFIRMATIVE DEFENSE

The States' claims are barred, in whole or in part, by the doctrines of laches, estoppel and waiver.

FIFTEENTH AFFIRMATIVE DEFENSE

The States' claims for damages are barred or should be reduced based on the States' failure to mitigate damages.

SIXTEENTH AFFIRMATIVE DEFENSE

The States' claims fail because, to the extent that the States attempt to seek equitable relief against Novartis, the States are not entitled to such relief because they have an adequate remedy at law.

SEVENTEENTH AFFIRMATIVE DEFENSE

The States' claims fail because, to the extent that civil penalties are sought against Novartis, such civil penalties cannot be sustained because an award of civil penalties would violate the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution and their equivalents under the Constitutions of the States.

EIGHTEENTH AFFIRMATIVE DEFENSE

The States' claims fail because, to the extent that the States are alleging fraud or similar conduct, they have failed to plead fraud with particularity.

NINETEENTH AFFIRMATIVE DEFENSE

The States' claims fail because their common law unjust enrichment claims are displaced by statute, and because the States fail to articulate how Novartis was unlawfully enriched.

TWENTIETH AFFIRMATIVE DEFENSE

The States' conspiracy claims fail because the States are unable to show an underlying actionable claim.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The States claims fail because their claims are too remote and speculative to form the basis for belief.

TWENTY-SECOND AFFIRMATIVE DEFENSE

The States' claims fail because they have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Novartis as alleged in the Complaint.

TWENTY-THIRD AFFIRMATIVE DEFENSE

The States' claims are barred in whole or in part, because the States' injuries were not proximately caused by the acts or omissions of Novartis, but, if they exist at all, were the result in whole or in part of intervening or supervening causes.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

To the extent the States obtain or have obtained recovery in any other proceeding predicated on the same factual allegations, the States are barred from seeking recovery against

Novartis based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Novartis reserves the rights to raise any additional defenses, cross-claims and third party claims not asserted herein of which it may become aware through discovery or other investigation.

PRAYER FOR RELIEF

WHEREFORE, Novartis Pharmaceuticals Corporation prays as follows:

That all claims contained in the States' Complaint against it be dismissed with prejudice.

That it be awarded costs and attorneys' fees.

That it have such other and further relief as this Court deems just and proper.

Dated: October 6, 2014

/s/ Michael A. Rogoff
Michael A. Rogoff
Manvin Mayell
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. No.: 212-836-8000

Faith E. Gay
Manisha M. Sheth
QUINN EMANUEL URQUHART &
SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
Tel. No.: 212-849-7000

Evan R. Chesler
Rachel G. Skaistis
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019
Tel. No.: 212-474-1000

Counsel for Defendant
Novartis Pharmaceuticals Corporation